K060643
p. 1 of 1

Atrion Medical Products, Inc.
1426 Curt Francis Road
Post Office Box 564
Arab, AL 35016
Tel 256 586 1580
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SECTION 5

JUL 12 2006

Atrion
Medical

SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: July 7, 2006

Device Name: Atrion Medical QL® Locking Syringe Device

Classification Name: Angiographic Injector and Syringe

Manufacturer: Atrion Medical Products, Inc.
PO Box 564, 1426 Curt Francis Road
Arab, AL 35016

Contact: Mr. Dan Clark,
Atrion Medical Products, Inc.
1426 Curt Francis Road
Arab, AL 35016
Telephone: (256) 317-2220
Fax: (256) 586-8529
Email: dclark@atrionmedical.com

Predicates:
Atrion Medical Products, Inc, QL® Inflation Device, K032840.
Merit Medical Systems, Inc. Viceroy™ Inflation device, K040138

Device Description:
The Atrion Medical QL® Locking Syringe Device consists of a plastic syringe with a screw-type plunger and a locking mechanism.

Intended Use: The Atrion Medical QL® Locking Syringe Device is intended for single use to inject fluid into and aspirate fluid from a balloon interventional device having a recommended balloon inflation volume.

Technological Characteristics:
The Atrion Medical QL® Locking Syringe Device has a capacity of 25ml, while the predicate devices have a range of 10ml or 60ml, depending on the predicate. There are no other significant technological characteristics that distinguish the two devices, and no differences that should pose a risk to patient safety.

Testing:
The materials of the device which contact the solution in use have been tested using USP guidelines and the results of these studies indicate that the product is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Atrion Medical Products, Inc.
c/o Mr. Dan Clark
Vice President
1426 Curt Francis Road
Arab, AL 35016

Re: K060643
Atrion Medical QL® Locking Syringe Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: II
Product Code: MAV
Dated: June 9, 2006
Received: June 9, 2006

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment for Item 4

SECTION 4

K060643

INDICATIONS FOR USE

510(k) Number (if known): K060643

Device Name: Atrion Medical QL® Locking Syringe Device

Indications For Use: The Atrion Medical QL® Locking Syringe Device is intended for single use to inject fluid into and aspirate fluid from a balloon interventional device having a recommended balloon inflation volume.

Prescription Use ___X____ AND/OR Over-The- Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060643